SEP - 8 2008

K082036

Bio-Rad Laboratories
Lyphochek Tumor Marker Plus Control
Premarket Notification Section 510(k)

1.0 DEVICE INFORMATION

Product Name:	Lyphochek Tumor Marker Plus Control
Common Name:	Clinical Chemistry Test Systems Quality control material (assayed and unassayed).

2.0 MEDICAL DEVICE ESTABLISHMENT

Manufacturing Facility:	Bio-Rad Laboratories
Address:	9500 Jeronimo Road Irvine, California 92618
Telephone:	949-598-1200
Fax:	949-598-1557

Establishment Registration No.: 2016706

3.0 DEVICE CLASS

Classification:	Class I
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

4.0 PERFORMANCE STANDARDS

None Require

5.0 PROPOSED LABELING

Included in this 510(k) notification is a copy of the proposed Lyphochek Tumor Marker Plus Control vial, box and insert labels (Appendices 3, 4 and 5).

6.0 STATEMENT OF SUBSTANTIAL EQUIVALENCE

Lyphochek Tumor Marker Plus Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert. This control is substantially equivalent to the following quality control material that is currently in the market:

Lyphochek Tumor Marker Control
Bio-Rad Laboratories
Irvine, California 92618

510(k) Number: K011579

A copy of the product insert for the above product can be found in Appendix 7.

7.0 COMPARISON OF THE NEW DEVICE WITH THE PREDICATE DEVICE

Lyphochek Tumor Marker Plus Control claims substantial equivalence to the Lyphochek Tumor Marker Control currently in commercial distribution (K011579).

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Laboratories Lyphochek Tumor Marker Plus Control (New Device)	Bio-Rad Laboratories Lyphochek Tumor Marker Control (Predicate Device)
Similarities		
Intended Use	Lyphochek Tumor Marker Plus Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Lyphochek Tumor Marker Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.
Storage (Unopened)	3 Years at 2 to 8°C	3 Years at 2 to 8°C
Reconstitute & Store at -20 to -70°C:	All analytes will be stable for 30 days at -20 to -70°C. There are no stability claims at -20 to -70°C for ACTH and Calcitonin.	All analytes will be stable for 30 days at -10 to -20°C with the following exception: NSE will be stable for 7 days.
Form	Lyophilized	Lyophilized
Matrix	Serum	Serum
Differences		
Levels	1, 2 and 3	1 and 2
Reconstitute & Store at 2 to 8°C	All analytes will be stable for 14 days at 2 to 8°C, with the following exceptions: • Carcinoembryonic Antigen (CEA) is stable for 11 days. • Free and Total PSA is stable for 7 days. • Thyroglobulin (Tg) is stable for 5 days. • ACTH and Calcitonin should be assayed immediately.	All analytes will be stable for 14 days at 2 to 8°C, with the following exceptions: • Ferritin and CA 27-29 will be stable for 6 days; • NSE will be stable for 3 days. • ACTH, Free PSA, PSA, and Calcitonin should be assayed immediately following reconstitution.
Analytes	**Contains Claims for the following:**	**Contains Claims for the following**
	• Adrenocorticotropic Hormone (ACTH)	• Adrenocorticotropic Hormone (ACTH)
	• Alpha Fetoprotein (AFP)	• Alpha Fetoprotein (AFP)
	• Aldosterone	• Aldosterone
	• Beta-2-Microglobulin	• Beta-2-Microglobulin (B2-M)
	• CA 15-3	• CA 15-3
	• CA 19-9	• CA 19-9
	• CA 27.29	• CA 27.29
	• CA 125	• CA 50
	• Calcitonin	• CA 72-4
	• Carcinoembryonic Antigen (CEA)	• CA 125
	• Ferritin	• Calcitonin
	• hCG Beta Subunit (β-hCG)/ hCG	• Carcinoembryonic Antigen (CEA)
	• Prostatic Acid Phosphatase (PAP)	• CASA
	• Prolactin	• Cyfra 21-1
	• Prostate Specific Antigen, Total (PSA)	• Ferritin
	• Prostate Specific Antigen, Free (Free PSA)	• Human Chorionic Gonadotropin (hCG)
	• Thyroglobulin (Tg)	• Human Chorionic Gonadotropin Beta Subunit (β-hCG)
		• Neuron Specific Enolase (NSE)
	Does not contain claims for the following:	• Prostatic Acid Phosphatase (PAP)
	• CA 50	• Prolactin
	• CA 72-4	• Prostate Specific Antigen, Total (Total PSA)
	• CASA	• Prostate Specific Antigen, Free (Free PSA)
	• Cyfra 21-1	**No claim is made for performance or stability**
	• Neuron Specific Enolase (NSE)	Thyroglobulin (Tg)

8.0 STATEMENT OF SUPPORTING DATA

Stability studies have been performed to determine the shelf life at 2 to 8°C, reconstituted at 2 to 8°C and reconstituted frozen at -20 to -70°C. Product claims are as follows:

8.1 Shelf Life at 2 to 8°C, all analytes will be stable for 3 years.

8.2 Reconstituted Stability at 2 to 8°C: Once the control is reconstituted, all analytes will be stable for 14 days when stored tightly capped at 2 to 8°C, with the following exceptions: Carcinoembryonic Antigen (CEA) will be stable for 11 days; Free and Total PSA will be stable for 7 days; Thyroglobulin (Tg) will be stable for 5 days; ACTH and Calcitonin should be assayed immediately following reconstitution.

8.3 Reconstituted Stability at -20 to -70°C: All analytes will be stable for 30 days after the control is reconstituted and stored tightly capped at -20 to -70°C. After use, discard the remaining material. There are no stability claims at -20 to -70°C for ACTH and Calcitonin.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 8 2008

Bio-Rad Laboratories
c/o Ms. Elizabeth Platt
9500 Jeronimo Road
Irvine, California 92618-2017

Re: k082036
Trade/Device Name: Lyphochek Tumor Marker Plus Control
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I reserved
Product Code: JJY
Dated: July 1, 2008
Received: July 17, 2008

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k082036

Device Name: **Lyphochek Tumor Marker Plus Control**

Indications For Use: **Lyphochek Tumor Marker Plus Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.**

Domestic Analytes Listed

- Adrenocorticotropic Hormone (ACTH)
- Alpha Fetoprotein (AFP)
- Aldosterone
- Beta-2-Microglobulin (B2M)
- CA 15-3
- CA 19-9
- CA 27.29
- CA 125
- Calcitonin
- Carcinoembryonic Antigen (CEA)
- Ferritin
- hCG Beta Subunit (β-hCG)/ hCG
- Prostatic Acid Phosphatase (PAP)
- Prolactin
- Prostate Specific Antigen, Total (PSA)
- Prostate Specific Antigen, Free (Free PSA)
- Thyroglobulin (Tg)

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Reena Philip
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k082036